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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,893	09/28/2001	Alessandra D'Azzo	SJ-01-0020	4347

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/966,893	D'Azzo et al.
Examiner	**Art Unit**
Christian L. Fronda	1652

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1 136 (a) In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U S C § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment See 37 CFR 1 704(b)

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above, claim(s) 1-7 and 14-20 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 8-13 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s)
4) ☐ Interview Summary (PTO-413) Paper No(s) ____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other

DETAILED ACTION

1. Claims 8-13 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8-13 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed 4/4/2003 (Paper No. 7) have been fully considered but they are not persuasive. Applicants' position is that the structure of proteins encompassed by the claims were well known in the art before the priority date of the instant application and that these structures do not need to be included in the specification. The Examiner respectfully disagrees for reasons of record and for the following reasons below.

Table 1 of the instant specification recites 34 diseases and their respective enzyme/protein deficiencies. However, the claims are directed to any polypeptide of any structure and function to be used in a composition for treating any lysosomal storage disorder wherein the claimed polypeptide is selectively imported into macrophages. It is not apparent that Table 1 of the specification provides a written description of the entire genus of lysosomal storage disorders and their respective enzyme/protein deficiencies. Furthermore, the specification does not provide a written description of administering any protein of any structure and function to treat any lysosomal storage disorder given that each of the diseases listed in Table 1 have different etiologies based on the various enzyme/proteins deficiencies. Thus, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Amending the claims to recite a composition comprising a protective protein/cathepsin A (PPCA) protein useful for treating Galactosialidosis may overcome this rejection.

4. Claim 8-13 rejected under 35 U.S.C. 112, first paragraph, because the specification, while

being enabling for composition comprising a protective protein/cathepsin A (PPCA) protein useful for treating Galactosialidosis, does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants' arguments filed 4/4/2003 (Paper No. 7) have been fully considered but they are not persuasive for reasons of record and for the following reasons below. The specification provides guidance and examples for injecting a baculovirus expressed and purified neuraminidase and PPCA into PPCA deficient mice resulting in increased activities of cathepsin A and neuraminidase. However, the nature and breadth of the claims encompass any pharmaceutical composition comprising any polypeptide of any structure and function to be used for treating any lysosomal storage disorder wherein the claimed polypeptide is selectively imported into macrophages.

The standard for meeting the enablement requirement is whether one of skill in the art can make or use the invention without undue experimentation. The amount of experimentation to make the claimed composition is enormous and undue and entails determining whether a particular disease is a lysosomal storage disorder disease, determining the etiology of the disease, and formulating a composition to treat or cure the disease. Table 1 of the specification shows various diseases with different enzyme/protein deficiencies. The specification does not teach that any one particular protein/enzyme can by used to treat every lysosomal storage disorder as encompassed by the claims.

Since such experimentation is not routine in the art, where the expectation of obtaining any pharmaceutical composition comprising any polypeptide of any structure and function which can be used to treat any patient having any lysosomal storage disorder is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the a specific composition which is effective in treating a patient having any lysosomal storage disease. Without such a guidance, the experimentation left to those skilled in the art is undue. Amending the claims to recite a composition comprising a protective protein/cathepsin A (PPCA) protein useful for treating Galactosialidosis may overcome this rejection.

Claim Rejections - 35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 8-13 stand rejected under 35 U.S.C. 102(a) as being anticipated by Sharp (WO 00/39150). The Sharp publication has been attached to the previous Office Action. The teachings of Sharp have been stated in the previous Office Action.

Applicants' arguments filed 4/4/2003 (Paper No. 7) have been fully considered but they are not persuasive. Applicant's position is that the Sharp reference fails to teach a pharmaceutical composition comprising a protein that has "unique post-translational modifications associated with insect cell production". The Examiner respectfully disagrees for reasons of record and for the following reasons below.

MPEP § 2113 states that for product-by-process claims, determination of patentability is based on the product itself and that the patentability of a product does not depend on its method of production. The claims do not recite the post translational modifications and the specific structural properties of the claimed polypeptide having a distinct glycosylation pattern, specifically, containing exposed mannose residues. Applicant must show an unobvious difference between the claimed invention and the composition taught by Sharp. Thus, the teachings of Sharp anticipate the claimed invention.

Amending the claims to recite a protective protein/cathepsin A (PPCA) protein with distinct and unique properties as supported by the specification which show an unobvious difference between the claimed invention and the composition taught by Sharp may overcome this rejection.

Conclusion

7. No claim is allowed

8. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF